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Attorneys for Defendants
C. R. Bard, Inc. and
Bard Peripheral Vascular, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability
Litigation

No. 2:15-MD-02641-DGC

**DEFENDANTS' MOTION AND
INCORPORATED MEMORANDUM
TO SEAL DOCUMENTS LODGED
UNDER SEAL BY PLAINTIFFS IN
SUPPORT OF PLAINTIFFS'
OMNIBUS SEPARATE STATEMENT
OF FACTS IN SUPPORT OF THEIR
RESPONSE TO DEFENDANTS'
MOTION FOR SUMMARY
JUDGMENT IN THE BELLWETHER
CASES**

(Assigned to the Honorable David G.
Campbell)

Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively
"Bard" or "Defendants") hereby submit this Motion to Seal and Memorandum relating to

documents lodged under seal by Plaintiffs in Opposition to Defendants' motions for Summary Judgment in support of Plaintiffs' Omnibus Separate Statement of Facts in Support of their Response to Defendants' Motion for Summary Judgment in the Bellwether cases. Plaintiffs lodged documents under seal both in relation to Plaintiffs Omnibus Separate Statement of Facts in Support of Their Response to Defendants' Motion[s] for Summary Judgment in Bellwether Cases (Dkt. 7950) and Plaintiffs' Errata. (Dkt. 8185).

In response to Bard's case specific motions for summary judgment, Plaintiffs filed an Omnibus Statement of Facts with over 150 documents that were produced by Bard or are transcripts of depositions discussing documents produced by Bard attached as exhibits.¹ The documents relate to Bard's development and analysis of its IVC filters, including design and development, regulatory, marketing and product assessment strategy. The documents subject to this motion were all produced subject to the Stipulated Protective Order entered in the MDL. If the documents are available publically through other means (including on other dockets), Bard is not seeking to seal them. Bard seeks to seal as redacted 32 documents/transcripts and to seal in their entirety only 8 documents. The documents Bard seeks to seal as redacted are identified on Bard's Notice of Filing Redacted (Dkt. 8443).

None of the Bellwether cases involve the Bard Recovery filter, yet more than half of the documents and transcripts filed by Plaintiffs relate only to that filter. The majority of the documents Bard seeks to seal redacted relate to the Recovery filter. In an apparent attempt to put hundreds of Bard documents in the public forum, Plaintiffs make reference to some of the Recovery documents (but not all) in their specific responses. For example, in the *Mulkey* (a case involving a Bard fourth generation filter, the Eclipse) response to Bard's Motion for Summary Judgment, Plaintiff cites to evidence of the migration results for the Recovery filter, but does not provide that information for the Eclipse.

¹ Plaintiffs also filed an Errata adding additional documents and pages to documents previously lodged. Bard redacted only the complete document.

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2 **1. Documents Bard submitted redacted (Dkt. 8443)**

3 Bard has submitted redacted versions of 32 of the documents.² These documents
4 include Bard's trade secrets regarding testing and development of its filters and internal
5 analysis of the performance of its products as described in the Declarations of Rob Carr
6 (Dkt 7343). For each document, Bard reviewed and redacted only the information that
7 related to its trade secrets and confidential information. The majority of each document is
8 available publically and thus available for the public to understand any ruling on the
9 motions for summary judgment. In fact, Bard submits that none of the redacted (or
10 sealed) documents are necessary for the public to understand the Court's ruling on the
11 motions for summary judgment. The issues in those motions relate, in large part, to public
12 information available or pure legal arguments. Nonetheless, using the guidelines used by
13 the FDA in producing documents pursuant to FOIA, Bard has redacted the documents.

14 **2. Documents Bard is seeking to seal entirely**

15 Bard seeks to seal Exhibits 26, 60, 77, 79, 95, 100, 112 and 115 in their entirety.
16 Bard has reviewed those documents in an attempt to redact them, but documents are
17 confidential in their entirety. Each of these exhibits is a Bard internal document
18 evaluating Bard's products. Exhibits 26, 60 and 115 address only the Recovery filter.
19 These documents include Bard's trade secrets regarding testing and development of its
20 filters and internal analysis of the performance of its products as described in the
21 Declarations of Rob Carr. The redacted and sealed information contained in the
22 documents required years for Bard to develop and is Bard's critical business information
23 which is not made public by Bard; would be of economic value to Bard's competitors.
24 Moreover, such value would extend not only to manufacturers of other IVC filters. Bard
25 invests very substantial sums of money in medical device research, testing (including
26 clinical testing), development, design, analysis, regulatory compliance, product

27
28 ² Bard also lodged redacted Plaintiffs' Omnibus Separate Statement of Facts with limited redactions to quotes from Bard documents.

1 evaluation, and marketing. If the information Bard has developed over the years
 2 pertaining to the Bard IVC Filters was obtained by its competitors, it would give an unfair
 3 economic advantage to those competitors. (*See*, Carr Decl.)

4 Protecting such information from public disclosure and from Bard's competitors
 5 will prevent Bard from sustaining serious economic and competitive harm, thereby
 6 representing a compelling reason to protect the documents' confidentiality. Further, while
 7 protecting Bard's confidential information, the redactions and documents under seal do
 8 not impair the public's ability to understand the ruling by the Court on Bard's Motion for
 9 Summary Judgment regarding Preemption. Accordingly, the Court should grant Bard's
 10 Motion to Seal.

11 **ARGUMENT AND CITATION OF AUTHORITY**

12 **A. The Court should seal the redactions and the documents because the** 13 **information is not necessary to understand any order on Bard's Motion** 14 **for Summary Judgment.**

15 In their Omnibus Statement of Facts in response to Bard's Motion for Summary
 16 Judgment, Plaintiffs refer to over 100 documents at issue in this motion, but many do not
 17 support their arguments or opposition. In fact in many instances, they simply cite to the
 18 fact that the document was created or exists. As such, the majority of the documents are
 19 not part of the analysis as to whether there is an issue of material fact, and are likewise not
 20 necessary for the Court to rule or for the public to be able to understand the ruling on
 21 Bard's Motion.³ As redacted, the documents meet the test of the balance necessary
 22 between the right of public access and the right to protect materials that "have traditionally
 23 been kept secret for important policy reasons." as recognized in *Kamakana v. City & Cnty.*
 24 *of Honolulu*, 447 F.3d 1172 (9th Cir. 2006).

27 ³ Bard objects to Plaintiffs simply citing to documents and filing them to put them in the
 28 public record without relying on them to support any factual allegation or claim, but
 nonetheless has redacted them and addresses them in this Motion.

B. Compelling Reasons Exist to Seal the Redacted Information and the Sealed Documents

Although the Ninth Circuit recognizes that the public has a “general right to inspect and copy public records and documents, including judicial records and documents,” *see, Kamakana*, 447 F.3d at 1179 (quoting *Nixon v. Warner Commc’ns, Inc.*, 435 U.S. 589, 597 & n. 7 (1978)), it also recognizes that the right of public access is not absolute and is overcome for materials that “have traditionally been kept secret for important policy reasons.” *Id.* (quotation omitted).

Such compelling reasons for sealing documents exist, for example, regarding proprietary, trade secret, and technical information, - the same type of information that Bard requests that the Court seal here. For example, in *In re Incretin-Based Therapies Products Liability Litigation*, No. 13MD2453 AJB (MDD), 2015 WL 11658712 (S.D. Cal. Nov. 18, 2015), the Court considered motions to seal related to cross-motions for summary judgment on the affirmative defense of preemption. The court found that compelling reasons existed to grant the motions to seal because the information was “confidential and proprietary information specific to each drug at issue and the development, testing, and regulation of each drug.” *Id.* at *3. The court found that such information “is readily subject to improper use resulting in significant competitive harm if disclosed publicly and available to competitors.” *Id.* Similarly, in *Spectrum Pharmaceuticals, Inc. v. Sandoz Inc.*, No. 2:12-CV-00111-GMN, 2014 WL 4202540, at *2 (D. Nev. Aug. 21, 2014), the court considered documents submitted in support of Sandoz’s motion for summary judgment. The documents related to an Abbreviated New Drug Application to the FDA, technical information about the product, and specific efforts to obtain FDA approval of the Application, including actual and planned confidential communications with the FDA. *Id.* The court found that information of this nature could injure the parties’ business, thereby constituting a compelling reason to grant the motion to seal. *Id.*

C. **The Redacted Information and Sealed Documents Contain Bard's Trade
Secrets and Other Confidential Information**

The redacted information and documents that Bard seeks to seal are the same type of information that the *In re Incretin-Based Therapies* and *Spectrum Pharmaceuticals* courts sealed at the dispositive motions stage. As with the other the redacted information and documents reflect confidential and proprietary information concerning the design, development, testing (including clinical testing), manufacture, and regulatory compliance activities concerning Bard IVC Filters; that detail Bard's product development activities, proprietary testing, and implementation of various proprietary processes and procedures. This redacted information and the documents took years for Bard to develop and reflect Bard's critical and confidential business information. Moreover, the information would be of economic value to Bard's competitors, not just for IVC filters, but also to manufacturers of other medical devices, as the information contained in the documents is not limited to IVC filters. *Id.* Bard invests substantial amounts of money in medical device research, testing, clinical trials, development, design, analysis, regulatory compliance, evaluation, and marketing. *Id.* Thus, if Bard's competitors obtained these documents, they would have an unfair economic advantage over Bard. *Id.*

Further, the categories of redacted information and the sealed documents at issue have long been recognized as containing information that requires sealing. *See e.g., Spectrum Pharm., Inc. v. Sandoz Inc.*, No. 2:12-CV-00111-GMN, 2014 WL 4202540, at *2 (D. Nev. Aug. 21, 2014) (sealing among other "proprietary business plans" and "business practices," "actual and planned confidential communications with the FDA"); *Clark v. Metro. Life Ins. Co.*, 2010 WL 1006823 (D. Nev. Mar. 16, 2010) (sealing "confidential internal business deliberations, organization, and capabilities"); *See also, Bracco Diagnostics, Inc. v. Amersham Health Inc.*, CIVA 3-6025FLW, 2007 WL 2085350 (D.N.J. July 18, 2007) ("regulatory correspondence" with the FDA, "cost and profit information," "unpublished clinical studies," and "internal analyses on products which are not intended for publication or dissemination"). *See also, Medicis Pharm.*

1 *Corp. v. Acella Pharm., LLC*, CV 10-1780-PHX-JAT, 2012 WL 2260928 at *2 (D. Ariz.
2 June 15, 2012) (sealing exhibits related to “Medicis’ marketing strategy, Acella’s product
3 formulation,...various e-mails and deposition transcripts, viscosity test data, sales and
4 marketing information, and various other documents” because “[m]uch of this information
5 has been previously sealed by the Court, has been designated as confidential by the parties
6 pursuant to the protective order in this case, or could otherwise potentially harm the
7 parties if released publicly because of its confidential and sensitive nature.”).

8 For each category of information listed above, Bard has continually and
9 successfully made efforts to protect the information from its competitors, in part because
10 it could be used by competitors against Bard. (See Carr Declaration Dkt. 7355 - at
11 13 &14). Additionally, Bard maintains the confidentiality of the documents and has
12 always sought a Protective Order or Confidentiality Agreement during the course of civil
13 lawsuits in order to protect their confidential, proprietary and trade secret information. (Id
14 at 7). Therefore, Bard has taken reasonable efforts to maintain confidentiality of these
15 documents and they should remain confidential.

16 Finally, Bard invests substantial sums of money in medical device research, testing,
17 development, design, analysis, regulatory compliance, and evaluation of its products and
18 does not make such information public. Thus, there is no doubt that the proprietary
19 information which Bard seeks to protect constitutes an overriding interest warranting
20 protection.

21 **D. The Resulting Prejudice From Public Disclosure Requires This Court’s**
22 **Protection**

23 As stated above, the proprietary redacted and sealed information contains highly
24 confidential and sensitive information about Bard’s design, product development, and
25 testing about the Bard Filters, and allowing unrestricted access to this information would
26 cause real and tangible harm to Bard, especially because they are not offered by Plaintiffs
27 to address any material fact. *See e.g., In re Eli Lilly & Co., Prozac Products Liability*
28 *Litigation*, 142 F.R.D. 454, 460 (S.D. Ind. 1992) (holding pharmaceutical company would

suffer harm if the manufacturing process it has expended time and money on developing became known to competitors); *Culinary Foods, Inc. v. Raychem Corp.*, 151 F.R.D. 297, 305 *order clarified*, 153 F.R.D. 614 (N.D. Ill. 1993) (“[D]isclosing Raychem’s product design modification and changes would decrease Raychem’s incentive to invest in safety devices. Raychem’s competitors would get free access to information which Raychem has spent a great deal of time and money producing and protecting”).

Bard invests considerable sums of money in medical device research, testing, development, design, analysis, regulatory compliance and evaluation. (Carr Decl. 14). There is no valid reason for Bard’s competitors to obtain the results of Bard’s product and marketing development without having to incur similar expenditures in time and money, since it would give them an unfair economic advantage. It is well documented that the current market for pharmaceuticals and medical devices is highly competitive. *See, e.g., In re Gabapentin Patent Litigation*, 312 F. Supp. 2d 653, 659 (D.N.J. 2004) (noting the pharmaceutical industry is highly competitive and granted protective order). An inadvertent disclosure, through open court records, of Bard’s information to any of its competitors would certainly injure Bard’s interest. This heightened level of competitiveness in the medical device market warrants protecting Bard’s efforts in developing such precise and valuable medical devices, such as the Bard Filters at issue here. *See, e.g., In re Gabapentin Patent Litigation*, 312 F. Supp. 2d 653 (holding that evidence supported finding that good cause existed for continued secrecy of materials).

To the contrary, because Bard has now redacted the documents, the public will not be impaired in its ability to understand the ruling by the Court on Bard’s Motion for Summary Judgment Regarding Preemption.

CONCLUSION

Therefore, compelling reasons exist for protection of Bard’s documents, and the Court should grant Bard’s Motion to Seal for the documents filed redacted in Dkt. 7845 and the redactions to Plaintiffs Separate Statement of Facts in Dkt. 7848. Bard also respectfully requests that the Court enter an Order sealing the five documents Bard seeks

1 to seal in its entirety.

2 This 27th day of October, 2017.

3
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18 **and Bard Peripheral Vascular, Inc.**
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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on October 27, 2017, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system which will send notification of such filing to all counsel of record.

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